COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11-IV-2004
C(2007)1693

NOT FOR PUBLICATION

COMMISSION DECISION

of 11-IV-2004

on the transfer of the marketing authorisation granted by Decision C(2001)818 for "TARGRETIN - bexarotene", a medicinal product for human use

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION DECISION

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on the transfer of the marketing authorisation granted by Decision C(2001)818 for "TARGRETIN - bexarotene", a medicinal product for human use

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 2141/96 of 7 November 1996[2] concerning the examination of an application for the transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EEC) No 2309/93, and in particular Article 6 thereof,

Having regard to the application submitted by Ligand Pharmaceuticals UK Ltd on 20 February 2007 under Article 3 of Regulation (EC) No 2141/96,

Whereas:

(1) The medicinal product "TARGRETIN - bexarotene", entered in the Community register of medicinal products under the numbers EU/1/01/178/001 and authorised by Commission Decision C(2001)818 of 29 March 2001, remains in compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3].

(2) A change of holder of the marketing authorisation for which the transfer application is made is a change of an administrative nature, which does not affect the scientific characteristics of the medicinal product already authorised.

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[1] OJ L 136, 30.4.2004, p. 1, Regulation as amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).

[2] OJ L 286, 8.11.1996, p. 6.

[3] OJ L 311, 28.11.2001, p. 67, Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).

(3) It is appropriate to set the date by which all the operations resulting from the transfer of the marketing authorisation must be completed.

(4) The European Medicines Agency has given a favourable opinion,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision (2001)818 of 29 March 2001 to Ligand Pharmaceuticals UK Ltd for the medicinal product "TARGRETIN - bexarotene", entered in the Community register of medicinal products under No(s) EU/1/01/178/001, is transferred to Eisai Ltd.

Article 2

Decision C(2001)818 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 3

1) The transfer referred to in Article 1 shall be authorised from the date of notification of this Decision.

2) All the operations resulting from this transfer must be completed by 30 April 2007 at the latest.

Article 4

This Decision is addressed to:
1. Eisai Ltd, 3 Shortlands, London, W6 8EE, United Kingdom
and
2. Ligand Pharmaceuticals UK Ltd, Innovis House, 108 High Street, Crawley, West Sussex RH10 1BB, United Kingdom.

Done at Brussels, 11-IV-2004

For the Commission
Heinz ZOUREK
Director-General